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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
GRASER, JENNIFER E	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 11/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/844,281	ROTHROCK ETAL.	
	Examiner	Art Unit	
	Jennifer E. Graser	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 August 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-49* is/are pending in the application.

4a) Of the above claim(s) *1-19 and 21-43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-20 and 44-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

1. Acknowledgment and entry of the Amendment submitted on 8/16/04 is made. Claims 16-20 and 44-49 are currently pending.

This application contains claims 1-15 and 21-43 drawn to a non-elected invention. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 112

2. Claims 16-19 and 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claims 16 and 19, the amino acid sequence of EA1, e.g., SEQ ID NO:1, should be inserted in the claims. The mere recitation of a name, i.e., EA1, to describe the invention is not sufficient to satisfy the Statute's requirement of adequately describing and setting forth the inventive concept. The claim should provide any structural properties, such as the amino acid sequence of the protein or molecular weight, which would allow for one to identify the protein without ambiguity. The mere recitation of a name does not adequately define the claimed antibody. At the very least, the claims should recite the "*B.anthracis* EA1 antigen".

Claim Rejections - 35 USC § 112-Enablement

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 20 and 45-49 are rejected under 35 U.S.C. 1 12, first paragraph, because the specification, while being enabling for 'a diagnostic kit comprising an isolated antibody which specifically binds to the EAI polypeptide consisting of the amino acid sequence set forth in SEQ ID NO:1", does not reasonably provide enablement for diagnostic kits comprising any antibodies which specifically react with vegetative cells or spores that specifically bind *B.thuringiensis* and not B.anthracis and not *B.anthracis* and *B.*cereus (claims 20 and 45-49). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

Claims 20 and 45-49 are broadly drawn to diagnostic kits comprising any antibodies which specifically react against spores or vegetative cells of B.thuringiensis, but not B.anthracis and/or B.cereus. However, the instant specification is only enabled for antibodies which specifically bind to the EAI protein of *B.anthracis* set forth in SEQ ID NO:1. The specification does not teach any other antibodies, but merely recites prophetic methods for developing antibodies specific to Bacillus species. Antibodies to species of Bacillus other than B.anthracis are described briefly on pages 6-7, yet no disclosure beyond the mere mention of the possibility of making such antibodies is provided. It would take one of skill in the art undue experimentation to identify a completely new unique antibody which displays no cross-reactivity to other members of its Genus. The specification has only enabled antibodies unique to the EAI polypeptide of B.anthracis. The EA1 polypeptide is unique to *B.anthracis*. There is a great deal of unpredictability in finding It would take undue experimentation for one of skill in the art to antibodies which can distinguish between the different species of Bacillus. There is very little guidance provided in the specification for finding an antibody unique to B.thuringiensis with no cross-reactivity to other species of Bacillus. There are no working examples provided with respect to other antibodies. While the skill of those in the art is high, the quantity of experimentation would be undue given the limited guidance provided by the specification. Genentech Inc. v. Novo Nordisk A/S (CAFC) 42 USPQZd 1001 clearly states: "Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be

workable. See Brenner v. Manson, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (stating, in context of the utility requirement, that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.") Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention". That requirement has not been met in this specification with respect to antibodies other than those which specifically to the EAI protein of *B.anthracis* set forth in SEQ ID NO:1.

Response to Applicants' Arguments:

Applicants argue that the claims have been amended to recite that the antibodies bind to EA1. This is not correct. Claims 20 and 45-49 are drawn to kits comprising antibodies which bind to spores or vegetative cells of *B.thuringiensis* and **not** *B.anthracis* and/or *B.cereus*. Applicants argue that a substitution of *B.thuringiensis* for *B.anthracis* would lead to the claimed invention. This has been fully and carefully considered but is not deemed persuasive. The specification teaches that the EA1 protein is unique to *B.anthracis* and that they have discovered that antibodies raised against it are not cross-reactive with the other species of *Bacillus* since EA1 is unique to *B.anthracis*. Accordingly, it is unclear how the substitution suggested by Applicant would work. The EA1 antigen does not exist in *B.thuringiensis* so a substitution, e.g., generating antibodies to an EA1 antigen of *B.thuringiensis*, would not be possible.

Additionally, no unique antigen for *B.thuringiensis* has been identified much less a non-cross-reactive antibody. Applicants suggestion amounts to invention, not mere experimentation. As stated above, Genentech Inc. v. Novo Nordisk A/S (CAFC) 42 USPQ2d 1001 clearly states: "Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. See Brenner v. Manson, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (stating, in context of the utility requirement, that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.") Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention." The enablement rejection of record does not imply, as summarized by Applicants, that antibodies against other species of *Bacillus* could not be generated. The rejection states that a unique *B.thuringiensis* antibody which does not react with *B.cereus or B.anthracis* when there is no teaching of a unique antigen of *B.thuringiensis* or demonstration of *B.thuringiensis* antibodies and their results in cross-reactive experiments. The title of the instant invention is "Anthrax specific antibodies", i.e., *B.anthracis*. The Applicants are claiming an antibody which they have not made, nor isolated (see instant claims 20 and 45-49). A hypothetical antibody is not allowable subject matter. No epitopes unique to *B.thuringiensis* have been identified in the specification. The idea of discovering a unique epitope which

can be used to identify a bacterial species is not a new concept. The discovery of a new epitope and the unique antibody directed against that epitope is a new invention. Applicants have not met this standard and their kits comprising prophetic *B.thuringiensis* antibodies are not enabled.

Claim Rejections - 35 USC § 112-Written Description

5. Claims 20 and 45-49 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims (20 and 45-49) are broadly drawn to diagnostic kits comprising any antibodies which specifically react against spores or vegetative cells of B.thuringiensis, but not B.anthracis and/or B.cereus. However, the instant specification is only enabled for antibodies which specifically bind to the *B.anthracis* EAI protein set forth in SEQ ID NO:1. The specification does not teach any other antibodies, but merely recites prophetic methods for developing antibodies specific to Bacillus species. Antibodies to species of Bacillus other than B.anthracis are described briefly on pages 6-7, yet no disclosure beyond the mere mention of the possibility of making such antibodies is provided. It would take undue experimentation for one of skill in the art to identify a completely new unique antibody which displays no cross-reactivity to other members of its Genus.

Genentech Inc. v. Novo Nordisk A/S (CAFC) 42 USPQZd 1001 clearly states: "Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. See Brenner v. Manson, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (stating, in context of the utility requirement, that "a patent is not a hunting license. It is. not a reward for the search, but compensation for its successful conclusion.") Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention."

With the exception of an isolated antibody which specifically binds to the protein consisting of the amino acid sequence set forth in SEQ ID NO:1, the skilled artisan cannot envision the detailed structure of the encompassed antibodies.

Therefore conception is not achieved until reduction of practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of making or isolating it. The antibody itself is required. A generic statement which defines a genus of antibodies only by their functional activity does not provide an adequate written description of the genus. While Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the

recitation of a representative number of molecules, usually defined by an amino acid/nucleotide sequence, falling within the scope of the claimed genus. An adequate written description of the claimed antibodies requires a precise definition, such as by structure, formula, chemical name, and/or physical properties, not a mere wish or plan for obtaining the claimed chemical invention.

Response to Applicants' Arguments:

Applicants argue that they have a provided a detailed and extensive discussion and protocol on how to make *Bacillus* species-specific antibodies in the specification on pages 6-7 and Examples on page 10. This has been fully and carefully considered but is not deemed persuasive. These passages teach a generic procedure for discovering novel epitopes and routine procedures for generating antibodies. Written description of a unique *B.thuringiensis* antibody which does not react with *B.cereus or B.anthracis* has not been provided. There is no teaching of a unique antigen of *B.thuringiensis*, much less an antibody generated against an epitope of this unique antigen. An adequate written description of the claimed antibodies requires a precise definition, such as by structure, formula, chemical name, and/or physical properties, not a mere wish or plan for obtaining the claimed chemical invention.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claim 16 and 44 is rejected under 35 U.S.C. 102(b) as being anticipated by Mesnage et al (Molec. Microbiol. 1997, 2346): 1 147-1 155) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Mesnage et al (Molec. Microbiol. 1997, 23(6): 1147-1155).

Mesnage et al teach antibodies to the Bacillus anthracis S-layer component, **EAI**. Antibodies to the surface array protein (Sap) are also taught. The diagnostic kits of claims 16 and 44 only require antibody to a spore or vegetative cell of Bacillus anthracis, and not B.thuringiensis and is therefore anticipated by the reference. The major cell antigen to which the isolated antibodies bind in the Mesnage reference is 100% identical to the EAI protein disclosed by Applicants. Applicants have disclosed in the instant specification that antibodies directed against this EAI protein are antibodies which bind to B.anthracis, but do not bind to B.thuringiensis. These antibodies are disclosed as the preferred embodiment in the instant specification. Although the reference does not specifically recite that the antibody to B.anthracis does not specifically react with B.thuringiensis, it inherently would not since the antigen to which it binds is specific to B.anthracis and the instant specification supports this finding. The antibodies to the EAI protein would be identical to Applicant's antibodies to the EAI antibody, i.e., the antibodies are raised against the same antigen. Since the Patent Office does not have the facilities for examining and comparing Applicant's antibody with the antibody of the prior art, the burden of proof is upon

applicants to show an unobvious distinction between the material structural and functional characteristics of the claimed antibody and the antibody of the prior art. See In re Best, 195 USPQ 430, 433 (CCPA 19&&). The assembly of the reagents to these assays in a diagnostic kit would have been obvious to one of ordinary skill in the art at the time the invention was made for convenience and storage capabilities. However, since the instant claims do not require any components other than the antibodies, the reference anticipates the claims. The phrase "diagnostic kit" is an intended use only. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Response to Applicants' Arguments:

Applicants argue that just because the claimed antibody and the antibodies taught by Mesnage specifically bind to the same antigen, EA1, does not meant they have the same properties. For example, they could bind to different epitopes, etc. This argument has been fully and carefully considered, but is not deemed persuasive. The language of the instant claims allow for the antibody to bind to any epitope or epitopes of the EA1 antigen. The antibody taught by Mesnage binds to an antigen which is 100% identical to the antigen to which Applicants' antibody binds. Accordingly, since the antibodies claimed are structurally the same, e.g, bind EA1 antigen, they would inherently possess the same cross-reactive properties. Since the Patent Office does not have the

facilities for examining and comparing Applicant's antibody with the antibody of the prior art, the burden of proof is upon applicants to show an unobvious distinction between the material structural and functional characteristics of the claimed antibody and the antibody of the prior art. See In re Best, 195 USPQ 430, 433 (CCPA 19&&).

Additionally, the specification stresses that in order to produce a species specific, non-cross reactive antibody, antibodies should be directed against distinguishing immunological features of *B.anthracis*, such as the EA1 antigen set forth in SEQ ID NO:1, which is specific to *B.anthracis* and is found on both spores and vegetative cells. Mesnage teaches an antibody which specifically binds to this EA1 antigen. Therefore, said antibody would inherently not cross-react with any other species of *Bacillus* which do not possess this antigen, e.g, *B.thuringiensis* and *B.cereus.*

Claim Rejections - 35 USC § 103

8. Claims 20 and 45-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kearney et al (WO 99/55842) in view of Loomis et al (WO 99/64863).

Kearney et al teach monoclonal antibodies which are specifically reactive to spores from different species of Bacillus. It is taught that the antibodies are highly specific and can discriminate between spores of potentially lethal organisms, such as B.anthracis, and other harmless closely related bacilli. See abstract. Example 14, page 19, teaches a monoclonal antibody which specifically reacts with B.thuringiensis, but not B.subtilis or B.anthracis. However, Kearney et

al does not particularly exemplify the use of a colloidal particle based lateral flow detection system.

Loomis et al teach that colloidal gold particle immunoassays have been successfully used in the prior art for many years. See pages 1-3. Loomis et al teach a more sensitive immunoassay test to what was known in the art.
It is a colloidal colorimetric flow through and lateral flow assay. The entire test is conducted on a test strep and the detection antibody is preferably a FAB fragment that has been labeled with a 50-100mm gold particle and immobilized on a test pad. See page 4. It is taught that the use of capture dendrimers to align and secure capture antibodies on a solid surface insure that no immunological activity of the capture antibody is sterically hindered.

It would have been prima facie obvious to one of ordinary skill in the art to use the monoclonal antibodies taught by Kearney in a colloidal lateral flow detection system taught by Loomis et al because Loomis et al teaches that it is a highly sensitive detection assay which is simple, sensitive and specific. The test strips would provide a much more efficient and easy assay then the ELISAS described in Kearney et al. The colloidal lateral flow detection system would have been an obvious modification as it was known in the art as a simple detection system.

Response to Applicants' arguments:

Applicants argument that Kearny does not teach an isolated antibody which specifically binds to EA1 antigen (new limitation herein) is not deemed

persuasive in overcoming the rejection because claims 20 and 45-49 does not recite this limitation.

9. Claims 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mesnage et al (Molec. Microbiol. 1997, 23(6): 1147-1 155) in view of Loomis et al (WO 99/64863).

Mesnage et al teach antibodies to the Bacillus anthracis S-layer component, EAI. It is disclosed that EAI constitutes the main lattice of the B.anthracis S-layer, and is the major cell-associated antigen. See abstract. Antibodies to the surface array protein (Sap) are also taught. It is taught that a Western blot assay suggested that the antibodies were highly specific to B.anthracis and did not cross-react. See page 1150-1151. Electron microscopy using grids with rabbit anti-EAI antibodies or rabbit anti-sap antibodies, or on anti-sap antibodies. The grids were incubated on colloidal gold anti-rabbit or anti-mouse coupled antibodies. The major cell antigen to which the isolated antibodies bind in the Mesnage reference is 100% identical to the EAI protein disclosed by Applicants. Applicants have disclosed in the instant specification that antibodies directed against this EAI protein are antibodies which bind to B.anthracis, but do not bind to B.thuringiensis. These antibodies are disclosed as the preferred embodiment in the instant specification. However, Mesnage et al does not particularly exemplify the use of these antibodies in a colloidal particle based lateral flow detection system.

Loomis et al teach that colloidal gold particle immunoassays have been successfully used in the prior art for many years. See pages 1-3. Loomis et al

teach a more sensitive immunoassay test to what was known in the art. It is a colloidal colorimetric flow through and lateral flow assay. The entire test is conducted on a test strep and the detection antibody is preferably a FAB fragment that has been labeled with a 5O-100mm gold particle and immobilized on a test pad. See page 4. It is taught that the use of capture dendrimers to align and secure capture antibodies on a solid surface insure that no immunological activity of the capture antibody is sterically hindered.

It would have been prima facie obvious to one of ordinary skill in the art to use the antibodies taught by Mesnage et al in a colloidal lateral flow detection system as taught by Loomis et al to detect B.anthracis because Mesnage et al teach that the antibodies are highly specific to B.anthracis and that EAI constitutes the main lattice of the B.anthracis S-layer, and is the major cell-associated antigen. One of ordinary skill in the art would have a reasonable expectation that a specific antibody developed against the major cell-associated antigen of a bacterium to be very effective in detecting the bacterium in a sample. Loomis et al teaches that it is a highly sensitive detection assay which is simple, sensitive and specific. The use of the EAI and/or Sap antibodies taught by Mesange in a colloidal lateral flow detection system would have been obvious as a B.anthracis detection system. The assembly of the reagents to these assays in a diagnostic kit would have been obvious to one of ordinary skill in the art at the time the invention was made for convenience and storage capabilities.

Response to Applicants' Arguments:

Applicants argue that just because the claimed antibody and the antibodies taught by Mesnage specifically bind to the same antigen, EA1, does not meant they have the same properties. For example, they could bind to different epitopes, etc. This argument has been fully and carefully considered, but is not deemed persuasive. The language of the instant claims allow for the antibody to bind to any epitope or epitopes of the EA1 antigen. The antibody taught by Mesnage binds to an antigen which is 100% identical to the antigen to which Applicants' antibody binds. Accordingly, since the antibodies claimed are structurally the same, e.g, bind EA1 antigen, they would inherently possess the same cross-reactive properties. Since the Patent Office does not have the facilities for examining and comparing Applicant's antibody with the antibody of the prior art, the burden of proof is upon applicants to show an unobvious distinction between the material structural and functional characteristics of the claimed antibody and the antibody of the prior art. See In re Best, 195 USPQ 430, 433 (CCPA 19&&).

Additionally, the specification stresses that in order to produce a species specific, non-cross reactive antibody, antibodies should be directed against distinguishing immunological features of *B.anthracis*, such as the EA1 antigen set forth in SEQ ID NO:1, which is specific to *B.anthracis* and is found on both spores and vegetative cells. Mesnage teaches an antibody which specifically binds to this EA1 antigen. Therefore, said antibody would inherently not cross-react with any other species of *Bacillus* which do not possess this antigen, e.g, *B.thuringiensis* and *B.cereus.*

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Correspondence regarding this application should be directed to Group Art Unit 1645. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Remsen. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15,1989). The Group 1645 Fax number is (703) 872-9306 which is able to receive transmissions 24 hours/day, 7 days/week.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E. Graser whose telephone number is (571) 272-0858. The examiner can normally be reached on Monday-Friday from 7:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0500.

J Graser 11/2/04

Jennifer Graser
Primary Examiner
Art Unit 1645